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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/552,272

04/19/2000

Li Fang

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10/25/2006

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EXAMINER

EPPS FORD, JANET L

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

78

Office Action Summary	Application No.	Applicant(s)	
	09/552,272	FANG ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,10 and 14-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5,6,10,14-19,23-28,32-37,50 and 53 is/are allowed.
- 6) ☒ Claim(s) 20-22,29-31,38-49,51,52 and 54-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The previously indicated allowability of claims 20-21, 29-31, 38-49, 51-52 and 55 is withdrawn for the reason set forth below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 20-22, 29-31, 38-49 and 51-52, and 54-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as filed, and the prior art as of the filing date of the instant specification describes the cspA, cspB, and the csdA genes. However, other than these genes the specification as filed does not provide a sufficient description of the full scope of nucleic acid sequence structures encoding cold-shock inducible genes such that the skilled artisan would be able to predict the structures of the claimed vectors that further comprise a second and/or third cold-shock inducible genes. It is noted that this issue was previously raised in the Office Action mailed 10-25-04, page 3:

Claims 16-57 require the structure of a first cold shock inducible gene, or a first and second cold shock inducible gene, and/or a cold box, and/or a down stream box. Although certain structures corresponding to these functional elements are disclosed in the specification as filed. The instant claims are not limited to those particular first and second cold shock inducible genes, and/or the cold box sequences, and/or the down stream box sequences described in the specification as filed. Absent evidence to the contrary, the instant claims encompass a genus of nucleic acid molecules that reads on all polymorphic and allelic variants of said first and/or second cold shock inducible genes, cold box sequences, and/or a down stream box sequences that are beyond the scope of the instant disclosure.

However, in the response filed 1-21-05, this issue was not adequately addressed, Applicants emphasized that the cold box and/or the down stream box have adequate description (see pages 21-23 of the response filed 1-21-05). However, there is no specific traversal in the reply filed 1-21-05 regarding the structure of the full scope of cold-shock inducible genes encompassed by the instant claims. As such the claims that read on a full-length sequence encoding a cold-shock inducible gene, other than *cspA*, *cspB*, and/or *csdA*, are included in the instant rejection, and remain rejected for the reasons of record. Although, these genes may comprise a substantial level of sequence similarity in the 5'UTR of these genes, as argued by Applicants on pages 12-15 of the response filed 8-06-04, this sequence similarity is not sufficient to establish possession of the full-length sequence of any and all cold-shock inducible genes, as suggested by the scope of the instant claimed.

In regards to claims 38-40, the recited methods are directed to methods for overexpressing a gene, this method comprises transforming bacteria with a nucleic acid vector comprising "a protein coding region identical to a sequence found in a second

nucleic acid molecule, wherein said first nucleic acid fragment enhances translation of a transcript derived from said protein coding region.” Claims 41-43, which depend from claims 38-40, recite “wherein said overexpression causes a reduction in the expression of at least one endogenous gene.” The structure of the protein coding region recited in claims 38-40 is unclear, which therefore renders the scope and structure of the transcripts derived from these protein coding regions uncertain. Moreover, if the structures of the protein coding regions are not adequately described, the structures of the “at least one endogenous proteins” that are reduced as a result of the overexpression of the protein coding regions, are also unclear, and lends to the conclusion that the ordinary skilled artisan would have been able to predict the full scope of the structures of these molecules at the time of filing of the instant application. Moreover, this observation also supports the conclusion that further experimentation is required to elucidate the full scope of the nucleic acid molecules corresponding to the protein coding regions, the transcripts derived from these sequences, and the endogenous proteins that are reduced in expression as a result of the overexpression of these sequences. Therefore, Applicant was not in possession of the full scope of the instantly claimed invention as of the filing date of the instant application.

As per, MPEP § 2163: “[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.”

Art Unit: 1633

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20-21, 38-40, 44-46, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-21 recite: "the sequence coding for said transcript.." there is lack of antecedent basis for this limitation in these claims, since the nucleic acid vectors recited in claims 16 and 19 do not recite a sequence encoding said transcript.

Claims 38-40 recite the phrase "a transcript derived from," the metes and bounds of the term "derived" as used in this context is vague and indefinite since the meaning of the term is not defined in either the specification as filed or in the claims.

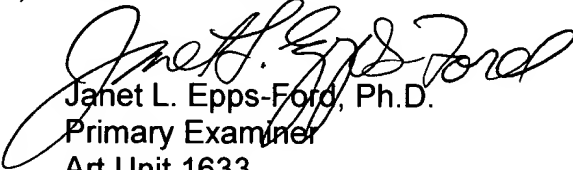
Claims 44-46, and 55 recite the phrase "a sufficiently low temperature.." The term "sufficiently" in claims 44-46 and 55 is a relative term, which renders the claims indefinite. The term "sufficiently" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Art Unit: 1633

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE